#### Idaho National Engineering and Environmental Laboratory

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Manual: 13A—Quality and Requirements

Management Program Documents

### 1. PURPOSE

This Program Requirements Document (PRD) identifies requirements and responsibilities for organizations that provide for the achievement and *verification* (see def.) of quality in *items* (see def.) produced and activities performed. See Appendix A for requirements basis.

## 2. APPLICABILITY

This PRD applies to the company organizations that prescribe, perform, or *verify* (see def.) *activities affecting quality* (see def.), including those having responsibility for planning and scheduling.

**NOTE**: Detailed organization charts are accessible via the Intranet on the company's home page that show the relationships of company organizations.

The QA PRDs apply to all organizations except for NRC licensed facilities and Waste Isolation Pilot Program activities, which are governed by separate QA program requirements. Activities of all organizations are divided into functional areas as shown in Table 1. Each functional area is assigned a senior manager who has the authority to ensure implementation of standards and requirements that fall within the scope of the assigned area, including the applicable quality assurance requirements contained in the QA PRDs. The company manuals contain implementing documents for each of these functional areas. QA requirements that are applicable to the functional area are addressed in each of the manuals and implemented in accordance with a *graded approach* (see def.) where its use is appropriate.

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Table 1. Functional Areas.

Manual No.	Functional Area	Manual No.	Functional Area
1	General Administration & Information	10 <b>B</b>	Engineering & Research – Safety
	Management		Analysis & Criticality Safety
2	Logistics and Property Management	11	Safeguards & Security
3	Financial Operations	12	Training & Qualification
4	Procurement	13	Quality
5	Project Cost and Schedule Controls	14	Safety and Health/Safety and Fire
			Protection/
6	Maintenance	14	Safety and Health/Occupational
			Health
7	Project Management	15	Radiation Protection
8	Environmental Protection and	16	Emergency Preparedness
	Compliance		
9	Operations	17	Waste Management
10 <b>A</b>	Engineering & Research – Conduct of	18	Closure Management
	Engineering, Configuration		
	Management, Systems Engineering, &		
	Engineering Change Control		

Responsibilities of managers who have principal roles in the quality assurance program are summarized below. Detailed definition of responsibilities for all managers is found in the manuals for the functional areas shown in Table 1.

## 3. RESPONSIBILITIES

# 3.1 Bechtel, BWXT Idaho, LLC, (BBWI) President, General Manager and Laboratory Director

The BBWI President, General Manager and Laboratory Director is responsible for:

- A. Ensuring that overall policy and management direction for the company *quality assurance* (QA; see def.) program is established and documented in appropriate *procedures* (see def.) and other implementing documents.
- B. Ensuring that resources necessary for effective implementation of the QA program are provided.
- C. Serving as final decision authority for QA *issues* (see def.) that are not resolved at subordinate management levels.

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- D. Ensuring that assessment of the status and adequacy of the overall QA program is accomplished and that results are provided to DOE-ID.
- E. Ensuring that the company organizational structure, functional responsibilities, levels of authority, and interfaces are clearly developed and established to achieve program objectives.

## 3.2 Environmental, Safety, Health and Quality Assurance General Manager

The Environmental, Safety, Health, and Quality Assurance (ESH&QA) General Manager is responsible for:

- A. Managing safety and health, environmental affairs, occupational medicine, radiological controls, security and emergency services, safeguards and security, independent oversight, and quality assurance.
- B. Defining policy and management direction for the establishment and implementation of the company QA program.
- C. Ensuring that such policy and direction is documented and disseminated.
- D. Authorizing such resources as are necessary for effective implementation of the QA program within ESH&QA.
- E. Mediating and resolving, if possible, QA program issues that have not been resolved at subordinate levels.
- F. Ensuring that QA division/department interfaces with DOE-ID, company organizations, *suppliers* (see def.), and contractors are established.
- G. Serving as the primary company interface with DOE-ID and other outside agencies on QA matters.
- H. Identifying quality problems; initiating, recommending, or providing solutions to quality problems; and verifying solutions to quality problems. [DOE/RW-0333P 1.2.2.F]
- I. Ensuring ESH&QA support of the goals of operational excellence and integrated safety management.

#### 3.3 Quality Assurance Director

The Quality Assurance Director is responsible for:

A. Setting company-level QA requirements.

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- B. Directing the company QA program.
- C. Verifying establishment and implementation of the QA program.
- D. Providing QA program development and maintenance services; quality engineering and *inspection* (see def.) services; *calibration* (see def.) services; and lessons learned, *corrective action* (see def.) management, and performance reporting and analysis functions.
- E. Performing the QA function for company activities and ensuring those activities meet DOE Orders on Quality Assurance and Office of Civilian Radioactive Waste Management (OCRWM) requirements.
- F. Interpreting and approving QA program requirements. [DOE/RW-0333P 1.2.2.D]
- G. Ensuring the company's QA program is defined and disseminated in approved procedures and other documentation.
- H. Ensuring that appropriate and effective interfaces are established between the company and the U.S. Department of Energy Idaho Operations Office regarding quality *issues* (see def.).
- I. Reporting internally and externally QA program deficiencies.
- J. Resolving QA issues that cannot be resolved at a lower level of management.
- K. Acting for the ESH&QA General Manager during his absence.

## 3.4 Nuclear Programs and Site Operations Vice President

The Nuclear Programs and Site Operations Vice President is responsible for:

- A. Managing nuclear operations and operational excellence, hazard identification, and spent nuclear fuels and waste management operations.
- B. Ensuring these responsibilities are handled in accordance with the applicable QA program requirements.

# 3.5 Research and Development Vice President and Deputy Laboratory Director

The Research and Development Vice President and Deputy Laboratory Director is responsible for:

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- A. Managing strategic management and the chief scientist, nuclear and energy systems, national security, environmental and energy sciences, and environmental technology and engineering.
- B. Ensuring that these responsibilities are handled in accordance with the applicable QA program requirements.

#### 3.6 Environmental Management Programs Vice President

The Environmental Management Programs Vice President is responsible for:

- A. Managing the environmental restoration program, high level waste program, spent nuclear fuel program, waste management program, and environmental management program integration.
- B. Ensuring that these responsibilities are handled in accordance with the applicable QA program requirements.

#### 3.7 Technical Services Vice President

The Technical Services Vice President is responsible for:

- A. Project management, construction management, engineering, the infrastructure and maintenance programs, information resource management and support services.
- B Ensuring that these responsibilities are handled in accordance with the applicable QA program requirements.

#### 3.8 Business Management Vice President and Chief Financial Officer

The Business Management Vice President and Chief Financial Officer is responsible for:

- A. Managing financial operations, planning and controls, and supply chain management and contracts.
- B. Ensuring these responsibilities are handled in accordance with the applicable QA program requirements.

## 3.9 Supply Chain Management and Contracts Director

The Supply Chain Management and Contracts Director is responsible for:

A. Establishing, maintaining, and providing oversight of a cost-effective and compliant supply chain and contract system at the INEEL.

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- B. Developing and maintaining standards and procedures for supply chain and contracts management.
- C. Ensuring supply chain and contract systems and processes are aligned with other management systems and deployed consistently across the INEEL.
- D. Negotiating and accepting INEEL contract changes.
- E. Ensuring these responsibilities are handled in accordance with the applicable QA program requirements.

# 4. **REQUIREMENTS**

### 4.1 Company Application

The requirements identified in this subsection (4.1) apply to the entire company unless exempted by INT-17, QA PRD Introduction, Subsection 2.

#### **4.1.1 Basic**

- 4.1.1.1 Responsibilities for the establishment and implementation of the quality assurance program *shall* (see def.) be defined. The organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality shall be documented. [NQA-1-1997, Requirement 1, 100]
- 4.1.1.2 The QA organization shall be responsible for verifying the proper establishment and execution of the QA program.

  [DOE/RW-0333P 1.2.2.G]
- 4.1.1.3 Where more than one organization is involved in the execution of activities, the responsibilities, interfaces, and authority of each organization shall be clearly defined and documented. [NQA-1-1997, Requirement 1, 300 1s]
- 4.1.1.4 The external interfaces between organizations and internal interfaces between organizational units, and changes thereto, shall be documented. [NQA-1-1997, Requirement 1, 300 2s]
- 4.1.1.5 The senior management position responsible for quality assurance program development, implementation, assessment, and improvement shall be assigned and identified. This position shall [DOE Order 414.1A Attachment 1, 1.(a)(1)]:

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- A. Be occupied by an individual with appropriate knowledge and experience in management and QA. [DOE/RW-0333P 1.2.2.2s]
- B. Be at the same or higher organization level as the highest line manager directly responsible for performing work subject to the quality assurance program. [DOE/RW-0333P 1.2.2.A]
- C. Be sufficiently independent from cost and schedule considerations. [DOE/RW-0333P 1.2.2.B]
- D. Have the organizational freedom to effectively communicate with other senior management positions. [DOE/RW-0333P 1.2.2.C]
- E. Have no other assigned responsibilities unrelated to the QA program that would prevent full attention to QA matters. [DOE/RW-0333P 1.2.2.E]
- F. Have the authority to stop work when *significant conditions adverse to quality* (see def.) warrant such action. [DOE/RW-0333P 1.2.2.H]

#### 4.1.2 Structure and Responsibility

- 4.1.2.1 The organizational structure shall be such that [NQA-1-1997, Requirement 1, 201]:
  - A. Senior management establishes the overall expectation for effective implementation of the quality assurance program and is responsible for obtaining the desired end results. [NQA-1-1997, Requirement 1, 201(a)]
  - B. Quality is achieved and maintained by those who have been assigned responsibility for performing work. [NQA-1-1997, Requirement 1, 201(b); DOE/RW-0333P 1.2.3.1s]
  - C. Quality achievement is verified by those persons or organizations not directly responsible for performing the work. [NQA-1-1997, Requirement 1, 201(c); DOE/RW-0333P 1.2.3.2s]
  - D. Those responsible for verifying quality achievement have sufficient authority, direct access to management,

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organizational freedom, and access to work to perform their function(s). [NOA-1-1997, Requirement 1, 201(d)]

#### 4.1.3 Delegation of Work

4.1.3.1 The individual(s) or organizations responsible for establishing and executing a quality assurance program may delegate any or all of the work to others but shall retain responsibility therefor.

[NQA-1-1997, Requirement 1, 202; DOE/RW-0333P 1.2.4]

## 4.1.4 Resolution of Quality Disputes

4.1.4.1 Differences of opinion involving quality assurance program requirements shall be brought to the attention of the appropriate management and, if not resolved, shall be elevated progressively to successively higher levels of management. [DOE/RW-0333P 1.2.5]

#### 4.1.5 Records

4.1.5.1 All records generated by this document that are designated in implementing documents as *quality assurance records* (see def.) shall be controlled in accordance with PRD-5088, 17.1 Quality Assurance Records. [Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements]

# **4.2** Specific Requirements for DOE/RW-0333P QARD Revision 10 Applications

This subsection (4.2) contains additional requirements from the QARD (DOE/RW-0333P, Revision 10) which are specific to the Spent Nuclear Fuel Program.

# 4.2.1 Responsibilities of Affected Organizations

- 4.2.1.1 Organizations affected by OCRWM requirements are required to develop and maintain implementing documents. [DOE/RW-0333P 1.3.3.A.1s]
- 4.2.1.2 Each *affected organization* (see def.) shall prepare one or more *controlled documents* (see def.), accepted by quality assurance, that describes internal and *external organizational* [see def.] interfaces, organizational structures, requirements, and responsibilities for its scope of work. [DOE/RW-0333P 1.2]
- 4.2.1.3 Each affected organization shall identify the responsibilities and authorities of those organizations and management positions

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responsible for achieving and maintaining quality. [DOE/RW-0333P 1.2.1]

# 5. **DEFINITIONS**

Refer to LST-199, Definitions, in the QA PRD Manual for the definitions of the following terms:

activities affecting quality affected organization calibration controlled document corrective action external organization graded approach inspection issues item procedure quality assurance quality assurance records significant condition adverse to quality shall supplier training verify verification

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# 6. REFERENCES

ASME NQA-1-1997, Quality Assurance Requirements for Nuclear Facility Applications

DOE Order 414.1A, Quality Assurance, September 1999

DOE/RW-0333P, Office of Civilian Radioactive Waste Management, Quality Assurance Requirements and Description, Revision 10

# 7. APPENDICES

Appendix A, 1.1 Basis

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# APPENDIX A

## **Procedure Basis**

Source	Citation	Requirement	Comments
ASME NQA-1-1997, Quality Assurance Requirements for Nuclear Facility Applications, Requirement 1	100	4.1.1.1	Consensus Requirement (CR)
NQA-1-1997, Requirement 1	201	4.1.2.1	CR
NQA-1-1997, Requirement 1	201 (a)	4.1.2.1.A	CR
NQA-1-1997, Requirement 1	201 (b)	4.1.2.1.B	CR
NQA-1-1997, Requirement 1	201 (c)	4.1.2.1.C	CR
NQA-1-1997, Requirement 1	201 (d)	4.1.2.1.D	CR
NQA-1-1997, Requirement 1	202	4.1.3.1	CR
NQA-1-1997, Requirement 1	300 1s	4.1.1.3	CR
NQA-1-1997, Requirement 1	300 2s	4.1.1.4	CR
DOE Order 414.1A, Quality Assurance	Attachment 1, 1.a.(1)	4.1.1.5	CR
DOE/RW-0333P, Quality Assurance Requirements and Description for the Civilian Radioactive Waste Management Program, Revision 10	1.2	4.2.1.2	Specific Requirement (SR)
DOE/RW-0333P	1.2.1	4.2.1.3	SR
DOE/RW-0333P	1.2.2.2s	4.1.1.5.A	CR
DOE/RW-0333P	1.2.2.A	4.1.1.5.B	CR
DOE/RW-0333P	1.2.2.B	4.1.1.5.C	CR
DOE/RW-0333P	1.2.2.C	4.1.1.5.D	CR
DOE/RW-0333P	1.2.2.D	3.3.F	CR
DOE/RW-0333P	1.2.2.E	4.1.1.5.E	CR
DOE/RW-0333P	1.2.2.F	3.2.H	CR
DOE/RW-0333P	1.2.2.G	4.1.1.2	CR
DOE/RW-0333P	1.2.2.H	4.1.1.5.F	CR
DOE/RW-0333P	1.2.3.1s	4.1.2.1.B	CR
DOE/RW-0333P	1.2.3.2s	4.1.2.1.C	CR
DOE/RW-0333P	1.2.4	4.1.3.1	CR
DOE/RW-0333P	1.2.5	4.1.4.1	CR
DOE/RW-0333P	1.3.3.A.1s	4.2.1.1	SR
PRD-5088, 17.1 Quality Assurance Records	All	4.1.5.1	Summary of records requirements from NQA-1-1997, DOE/RW-0333P, and Company Imposed Requirements